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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,769	12/29/2000	Judith K. Gwathmey	G2000-7000	5078

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 12/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

751,769

Applicant(s)

GWATHMEY

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on 5/14/04
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-8, 10-12, 30-41 is/are pending in the application.
- Of the above claim(s) 1-8, 10-12, 30, 36-41 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 31-35 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5.14.04 has been entered.

Claims 1-8, 10-12 and 30-41 are pending.

Applicant's election with traverse of Group III (claims 31-35) in the reply filed on 8/23/04 is acknowledged. The traversal is on the ground(s) that the claims may all be searched together without undue burden because they all involve an iron chelator and a lipid carrier. This is not found persuasive because at the time applicant filed, she had little idea of what might be patentable. Applicant apparently considered that the mere combination of an iron chelator and a lipid carrier was patentable and provided the link between all dependent claims which included further limitations pertaining to targeting agents and subgenuses/species thereof. The prior art cited in the first action clearly shows that the simple combination of an iron chelator and lipid carrier is not patentable. Applicant is thus seeking claims to the combination of the iron chelator and lipid carrier along with particular subgenuses or species of targeting agents. The only feature of any claim that could provide for patentability over the prior art would be the nature of the targeting agent. The search for any of the Groups must therefore focus on the nature of the targeting agent and lipid carrier. Since the targeting agents for heart and in liver are substantially different from one another and do not appear to have members in common

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it would be an undue burden for the examiner to search and examine the inventions of multiple Groups.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's amendment of 5/14/04 has overcome previously stated rejections under 112 and 102. New grounds of rejection follow.

Claims 31-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 31 and 32 contain new matter by virtue of reciting "liver cell receptor".

This recitation creates a new subgenus of entities to be targeted on liver cells. Applicant provided a generic description of targeting the "liver" at page 4 line 33, without disclosing the chemical/ biological nature of any of the entities of liver cells/ tissue to be targeted. Applicant provided a more particular description recited as "liver carbohydrate receptors" at page 14, line 12. Since applicant has not modified "receptors" with the descriptor "carbohydrate" in claims 31 and 32, applicant has introduced new matter.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 32 the Markush group of receptors is improper because "a liver endothelial cell" is not a species of receptors.

Claims 31-33 and 35 are rejected under 35 U.S.C. 102(d) as being anticipated by Lau et al (ref A5) in light of Rohman (ref A7).

Lau et al teach (abstract) encapsulation of desferrioxamine (DF) in multilamellar or unilamellar liposomes, which are prepared with or without a galactosyl moiety incorporated into the lipid. The galactosyl liposomes appear to have a higher affinity than non-galactosyl liposomes for liver parenchyma (hepatocyte) cells (see abstract and page 515).

Rohman is relied upon for showing (see citation of ref. A7 infra) that galactosyl receptors are inherently "asialoglycoprotein" receptors, as recited in claim 32.

Regarding claim 33, it is noted that desferrioxamine is a species of bacterial siderophores; hence, both of these recited Markush group members are taught.

Claims 31-33 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Rohman (ref A7).

Rohman teaches multilamellar and unilamellar liposomes prepared with a galactosyl targeting agent. These can be targeted to liver parenchyma cells (hepatocytes). See page 212, first full paragraph, indent c). Note therein Rohman's citation of references 3) and 4), listed in full at page 22; this shows that galactosyl receptors are "asialoglycoprotein" receptors, as recited in claim 32.

Claims 31-33 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Rohman et al (ref A8) in light of Rohman (A7).

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Rohman et al disclose the same liposomes as Rohman (A7) cited supra. See ref. A8 at page 286. Rohman (A7) is relied upon for showing, as noted supra, that galactosyl receptors are inherently "asialoglycoprotein" receptors, as recited in claim 32.

Claim 34 has not been rejected over any of the above cited prior art references. From the teachings of each, one can not determine what might be the concentration of the chelator within the liposome.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (571) 272-0849. The examiner can normally be reached on Monday to Thursday from 8 AM to 5:30 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/LR
November 12, 2004

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
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